SUPPORTING STATEMENT
Authorization Request Forms/Certification/Letter of Medical Necessity
Opioid Medications/Compounded Drugs

1240-0055

A. Justification:

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collections. Attach a copy of the appropriate section of each statute and of each regulation mandating or authorizing the collection of information.

Background

On March 23, 2016, the President of the United States, Barack Obama, responding to the escalation of prescription opioid abuse and the heroin epidemic, announced several actions taken by his Administration to address the epidemic, including steps to expand access for treatment, prevent overdose deaths and increase community prevention strategies.

The President had previously announced in October 2015 that several initiatives would be undertaken by the federal government as it related to opioid abuse and the heroin epidemic, noting that the Centers for Disease Control and Prevention (CDC) reported that overdose deaths involving prescription opioids quadrupled between 1999 and 2013, with more than 16,000 deaths in 2013. The CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction.

In 2013, the President also signed a law to provide greater federal oversight over compounding pharmacies that custom mixed medication in bulk for patients who may have benefitted from prescriptions specific to their individual medical needs. *See* Compounding Quality Act, Pub. L. No. 113-54, 127 Stat. 587 (2013). Compounded medications (which may contain opioids) have two or more ingredients and are offered as an alternative to FDA-approved medications that do not meet an individual patient's health needs, such as when a patient has an allergy that requires a medication to be made

without a certain dye. *See Compounding and the FDA: Questions and Answers*, FDA,

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm.

Compounded drugs are not FDA-approved. This means that the FDA does not verify the safety or effectiveness of compounded drugs. Consumers and health professionals rely on the drug approval process to ensure that drugs are safe and effective and made in accordance with Federal quality standards. Compounded drugs also lack an FDA finding of manufacturing quality before such drugs are marketed.

Health risks associated with compounded drugs include the use of ingredients that may be sub- or super-potent, contaminated, or otherwise adulterated. Additionally, patients may use ineffective compounded drugs instead of FDA-approved drugs that have been shown to be safe and effective.

Impacts on the FECA Program

The Federal Employees' Compensation Act (FECA), 5 U.S.C. 8101 et seq., provides compensation benefits to Federal employees for work-related injury/illness and to their surviving dependents if a work-related injury/illness results in the employee's death. Section § 8145 provides the Secretary of Labor the authority to delegate the responsibility to administer the FECA program to OWCP; through this delegation OWCP has the authority and the responsibility to decide all questions arising under the FECA. 5 U.S.C. § 8145.

Section 8103 provides:

The United States shall furnish to an employee who is injured while in the performance of duty, the services, appliances, and supplies prescribed or recommended by a qualified physician, which the Secretary of Labor considers likely to cure, give relief, reduce the degree or the period of disability, or aid in lessening he amount of the monthly compensation. 5 U.S.C. § 8103.

In recent years, the FECA program has seen an exponential increase in the number of compounded drug prescriptions being submitted for payment in workers' compensation claims. A greater number of claimants are receiving these medications and are receiving them more frequently, increasing concern about the efficacy and safety of these prescriptions for our injured federal workers. These major health care issues has encroached upon the OWCP with escalation in program costs and with the use of compounded medications within the federal agencies OWCP services.

A number of injured workers receiving benefits under the FECA program are prescribed opioid medication. While most prescriptions are short term in nature, some patients remain on these habit-forming medications for a long period of time.

Statutorily, FECA is mandated to provide medically necessary supplies and services to treat work related injuries. However, the FECA statute gives broad discretionary authority to determine the medical necessity of supplies and services used to treat work related injuries. Because of the increase in compounded drugs and safety concerns for both compounded drugs and opioids, the Department of Labor deems it necessary to more closely review the medical necessity of these medications in FECA claims by instituting a pre-authorization process. Requiring Prior Authorization will assist OWCP in determining whether the prescribed medication will assist in curing, giving relief, and lessening the degree of disability. These forms will further strengthen medical management procedures for prescription drugs, assist our stakeholders in controlling costs from medically unnecessary treatments, and lessen the impact of potential drug addiction and medical fraud.

As a major goal of the FECA program is to return an injured employee back to employment as soon as medically feasible. The forms will serve as a means for injured workers to receive opioids and compounded drugs only where medically necessary and simultaneously give OWCP greater oversight in monitoring their use. FECA further provides OWCP the authority to conduct such investigation as necessary before making an award of compensation (including the need for

medical treatment by certain prescription drugs). 5 U.S.C. § 8124(a)(2). Finally 5 U.S.C. § 8149 provides OWCP the authority to prescribe rules and regulations necessary for the administration of FECA. The Department has issued regulations relating to its authority to require prior authorization for medical treatment which will be applied through these forms for compounded drugs and opioids. (20 CFR 10.310, 10.800 & 10. 809).

References:

https://www.dol.gov/owcp/dfec/regs/statutes/feca.htm

https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=c131552afa82be329e42e2c9d62a41c8&rgn=div5&view=text&node=20:1.0.1.2.2&idno=20

The two forms to fulfill these requirements and obligations under the FECA are:

1. CA- 26. Authorization Request Form and Certification/Letter of Medical Necessity for Compounded Drugs.

2. CA- 27. Authorization Request Form and Certification/Letter of Medical Necessity for Opioid Medications.

The CA-27 is part of an Overall Opioid Policy with a 4 point Strategic Plan using: 1) Effective controls; 2) Tailored treatment; 3)Impactful communications and 4) Fraud Detection. Through use of this form and this broader plan, the FECA program has experienced a significant decrease in opioid prescriptions.

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

The CA-26 and the CA-27 are similar in nature, and are required to be certified by a claimant's treating physician. The treating physician will be required to indicate all ingredients that are being prescribed, whether the

medication and the ingredients, as applicable, are medically necessary or not (with consideration of non-opioid and non-compounded drugs as alternative dispensing methods). The physician must also consider cost effectiveness as part of his or her authorization/certification request for compounded drugs.

These forms are required to be on file each time the treating physician prescribes such medications, and maintained in a database held by our medical billing services contractor and passed along to DOL Medical Benefit Claims Examiners when their review is required. In order to complete and submit this information, the treating physician must be enrolled and registered with our medical services contractor provider.

The forms themselves permit OWCP to more easily track the volume, type, and characteristics of opioids and compounded drugs used in the FECA program. As noted, these forms require the certification/signature of the treating physician and maintained by the medical billing services contractor.

OWCP has a contracted vendor to provide medical bill processing services for their benefit programs. This program reimburses medical and non-medical providers for their services rendered for the use and treatment of a claimant’s compensable condition.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g. permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

While OWCP has information on its website concerning these forms, the form itself will not be accessible on a public domain website, but found on our contracted medical vendor’s website. In order to access the form, the treating physician is required to be registered with our program. The treating physician will have the ability to electronically submit the form to our contracted medical

vendor. The electronic version is in the same format as the paper form.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item A.2 above.

There is no similar information available.

5. If the collection information impacts small businesses or other small entities, describe any methods used to minimize burden.

This information collection has been streamlined to obtain the necessary information while imposing the minimum burden on the respondent. This information collection does not have a significant economic impact on a substantial number of small entities.

These forms are electronically formatted, and transmitted with the use of electronic signature by the providers to our contracted medical provider. This enhancement reduces the time and costs of mailing the documents.

6. Describe the consequence of Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

Failure to impose a preauthorization process may result in increases in the use of compounded and opioid drugs, raising safety and cost concerns.

7. Explain any special circumstance required in the conduct of this information collection.

There are no special circumstances for this information collection.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8 (d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe

actions taken by the agency in response to these comments.

A Federal Register Notice inviting public comment was published on November 6,2019 (84 FR 59842). Comments were/were not received.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

No payments or gifts are made to respondents to furnish the information.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulations, or agency policy.

The information collected by these requests is maintained in FECA claim files, which are fully protected under the Privacy Act. Records pertaining to compensation cases are covered under the Privacy Act. The Privacy Act Notice is provided on each of the forms. All forms used to initiate a compensation claim contain a statement advising the claimant of the provisions of the Privacy Act. The applicable Privacy Act system of records is called DOL/GOVT-1.

See web site: https://www.dol.gov/sol/privacy/dol-govt-1.htm

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary; the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

No questions of a sensitive nature concerning sexual preference, religion, etc. are requested. However, while questions regarding a patient’s diagnosis and prescribed medications may be considered, this information is covered under the Privacy Act System of Records. Specifically, this System may contain the following kinds of records: reports

of injury by the employee and/or employing agency; claim forms filed by or on behalf of injured Federal employees or their survivors seeking benefits under FECA; forms authorizing medical care and treatment; other medical records and reports; bills and other payment records; compensation payment records; formal orders for or against the payment of benefits; transcripts of hearings conducted; and any other medical, employment, or personal information submitted or gathered in connection with the claim.

As previously addressed, requesting this information assists OWCP in determining whether prescriptions are medically necessary for the treatment of the injury/occupational disease and that such prescriptions are being recommended for medical diagnosis(es) that the OWCP has accepted as being compensable under the Act.

12. Provide estimates of the hour burden of the collection of information. The statement should:

- ***Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not make special surveys to obtain information on which to base burden estimates. Consultation with a sample of potential respondents is desirable. If the burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated burden and explain the reason for the variance. Generally, estimates should not include burden hours for customary and usual business practices.***

  Based on data provided by our contracted medical billing provider, our estimate is based on average number of responses/burden hours on prescription data during the FY2018.

Form	***Time to Complete (min)***	***Number of Responses***	***Burden Hours***
CA-26	***30***	***500****	***250***

CA-27	***30***	***45,100****	***22,550***
Total		***45,600***	***22,800***

Calculation of burden hours

CA-26: 30 minutes X 500/60 = 250
CA-27: 30 minutes x 45,100/60 = 22,550

**** DOL assumes approximately 500 Form CA-26 submissions will occur per year based on historical submissions. DOL assumes approximately 11,000 persons will respond to Form CA-27 and will each make an average of 4.1 submissions, for a total of 45,100 responses.***

The combined burden hours have been calculated to be 22,800. We have estimated the cost of the burden hours at $2,234,856.) using the current mean hourly wage of ($98.025) reported for physicians and surgeons (based on Bureau of Labor Statistics data for May 2018)

Reference: https://www.bls.gov/oes/current/oes291069.htm

$98.02 x 22,800 = $2,234,856.

13. Annual Costs to Respondents (capital/start-up & operation and maintenance).

These forms are electronically submitted to our medical services vendor, therefore, the respondents incur no operation or maintenance costs.

14. Provide estimates of annualized cost to the Federal government.

Process/Review Costs:

-- By OWCP staff: The average hourly wage for the Claims Examiner is a GS11/4 at $32.80 per hour.

Reference: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2019/RUS_h.pdf

It is estimated that Claims Examiners will need to review all of the CA-26 forms, which will take an average of 10 hours to

process. It is estimated that Claims Examiners will need to review all CA-27 forms, which will take an average of 4 hours to process.

Form	***Time to Process/Review***	***Number of Responses***	***Costs***
CA-26	***10 hours***	***500***	***$ 164,000***
CA-27	***4 hours***	***45,100***	***$5,917,120***
Total		***45,600***	***$6,081,120***

-- By Contracted Medical Services Vendor: The contractor cost to process the forms is $951,382 per year.

Federal Cost Estimates:

Printing costs: There is no printing cost associated with either of these forms since both forms will only be stored on our contracted medical services website. When needed, updates are issued in the form of bulletins to the programs' provider community. Printing and mailing costs for provider notices and bulletins are built into the contract that OWCP has with the contracted medical services vendor.

Mailing and Envelope Cost: There are no mail costs involved as these forms are available for electronic completion and submission via our contracted medical services vendor.

Total Federal Cost*: $7,032, 502 (OWCP/Contracted Medical Vendor = $6, 081, 120 + $951,382)*

15. Explain the reasons for any program changes or adjustments.

There is a reduction in the number of respondents from the previous submission of 170,000 to 45,600, a difference of 124, 400. Accordingly, the previous burden hours of 85, 000 is adjusted to 22, 800, a decrease of 62,200. There are no associated burden costs. The adjustments are reflective of enhanced oversight by OWCP for both compound and opioid prescriptions that includes the implementation of the four point strategic plan noted above.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the

time schedule for the entire project, including beginning and ending dates of the collection information, completion of report, publication dates, and other actions.

There are no plans to publish this collection of information.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

This ICR does not seek a waiver from the requirement to display the expiration date.

18. Explain each exception to the certification statement identified in ROCIS.

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

Statistical methods are not used in these collections of information.